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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,852	07/03/2002	Jurgen Marki	GKS-101.0(7911/83687)	1442
24628	7590	11/12/2004	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			MAYER, SUZANNE MARIE	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/936,852

**Applicant(s)**

MARKI ET AL.

**Examiner**

Suzanne M. Mayer, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/049,988.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-20, 22 and 32-33, drawn to the DNA of *Haliotis tuberculata* hemocyanin protein 1 (HtH1), where a single nucleic acid sequence must be elected from SEQ ID Nos: 1-8, 49 and 80-87.

Group II, claims 1-20, 22 and 32-33, drawn to the DNA of *Haliotis tuberculata* hemocyanin protein 2 (HtH2), where a single nucleic acid sequence must be elected from SEQ ID Nos: 9-15, 50-53 and 88-95.

Group III, claims 1-20, 22 and 32-33, drawn to the DNA of *Megathura crenulata* hemocyanin protein 1 (KLH1), where a single nucleic acid sequence must be elected from SEQ ID Nos: 17-19, 54-56 and 96-101.

Group IV, claims 1-20, 22 and 32-33, drawn to the DNA of *Megathura crenulata* hemocyanin protein 2 (KLH2), where a single nucleic acid sequence must be elected from SEQ ID Nos: 20-24, 57-62 and 102-108.

Group V, claims 20-31 and 34-38, drawn to the peptides of *Haliotis tuberculata* hemocyanin protein 1 (HtH1) and pharmaceutical compositions containing the peptides, where a single amino acid sequence must be elected from SEQ ID Nos: 25-32 and 63-64.

Group VI, claims 20-31 and 34-38, drawn to the peptides of *Haliotis tuberculata* hemocyanin protein 2 (HtH2) and pharmaceutical compositions containing the peptides, where a single amino acid sequence must be elected from SEQ ID Nos: 33-39 and 65-68.

Group VII, claims 20-31 and 34-38, drawn to the peptides of *Megathura crenulata* hemocyanin protein 1 (KLH1) and pharmaceutical compositions containing the peptides, where a single amino acid sequence must be elected from SEQ ID Nos: 40-43 and 69-73.

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Group VIII, claims 20-31 and 34-38, drawn to the peptides of *Megathura crenulata* hemocyanin protein 2 (KLH2) and pharmaceutical compositions containing the peptides, where a single amino acid sequence must be elected from SEQ ID Nos: 44-48 and 74-79.

Group IX, claims 20-31 and 34-38, drawn to the peptides of *Haliotis tuberculata* hemocyanin protein 1 (HtH1) encoded by a DNA sequence and pharmaceutical compositions containing the peptides, where a single sequence must be elected from SEQ ID Nos: 1-8, 49 and 80-87.

Group X, claims 20-31 and 34-38, drawn to the peptides of *Haliotis tuberculata* hemocyanin protein 2 (HtH2) encoded by a DNA sequence and pharmaceutical compositions containing the peptides, where a single sequence must be elected from SEQ ID Nos: 9-15, 50-53 and 88-95.

Group XI, claims 20-31 and 34-38, drawn to the peptides of *Megathura crenulata* hemocyanin protein 1 (KLH1) encoded by a DNA sequence and pharmaceutical compositions containing the peptides, where a single sequence must be elected from SEQ ID Nos: 17-19, 54-56 and 96-101.

Group XII, claims 20-31 and 34-38, drawn to the peptides of *Megathura crenulata* hemocyanin protein 2 (KLH2) encoded by a DNA sequence and pharmaceutical compositions containing the peptides, where a single sequence must be elected from SEQ ID Nos: 20-24, 57-62 and 102-108.

Group XIII, claim 39, drawn to a hemocyanin peptide from *Haliotis tuberculata* hemocyanin protein 1 (HtH1) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 1-8, 49 and 80-87.

Group XIV, claim 39, drawn to a hemocyanin peptide from *Haliotis tuberculata* hemocyanin protein 2 (HtH2) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 9-15, 50-53 and 88-95.

Group XV, claim 39, drawn to a hemocyanin peptide from *Megathura crenulata* hemocyanin protein 1 (KLH1) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 17-19, 54-56 and 96-101.

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Group XVI, claim 39, drawn to a hemocyanin peptide from *Megathura crenulata* hemocyanin protein 2 (KLH2) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 20-24, 57-62 and 102-108.

Group XVII, claims 40-41, drawn to a liposome containing DNA from *Haliotis tuberculata* hemocyanin protein 1 (HtH1) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 1-8, 49 and 80-87.

Group XVIII, claims 40-41, drawn to a liposome containing DNA from *Haliotis tuberculata* hemocyanin protein 2 (HtH2) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 9-15, 50-53 and 88-95.

Group XIX, claims 40-41, drawn to a liposome containing DNA from *Megathura crenulata* hemocyanin protein 1 (KLH1) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 17-19, 54-56 and 96-101.

Group XX, claims 40-41, drawn to a liposome containing DNA from *Megathura crenulata* hemocyanin protein 2 (KLH2) encoded by a DNA sequence used as a carrier for a medicament, where a single sequence must be elected from SEQ ID Nos: 20-24, 57-62 and 102-108.

Group XXI, claim 42, drawn to antibodies to a *Haliotis tuberculata* hemocyanin protein 1 (HtH1) encoded by a DNA sequence, where a single sequence must be elected from SEQ ID Nos: 1-8, 49 and 80-87.

Group XXII, claim 42, drawn to antibodies to a *Haliotis tuberculata* hemocyanin protein 2 (HtH2) encoded by a DNA sequence, where a single sequence must be elected from SEQ ID Nos: 9-15, 50-53 and 88-95.

Group XXIII, claim 42, drawn to antibodies to a *Megathura crenulata* hemocyanin protein 1 (KLH1) encoded by a DNA sequence, where a single sequence must be elected from SEQ ID Nos: 17-19, 54-56 and 96-101.

Group XXIV, claim 42, drawn to antibodies to a *Megathura crenulata* hemocyanin protein 2 (KLH2) encoded by a DNA sequence, where a single sequence must be elected from SEQ ID Nos: 20-24, 57-62 and 102-108.

Group XXV, claims 43-44, drawn to a screening method to identify a tumour-specific DNA by using DNA from *Haliotis tuberculata* hemocyanin protein 1 (HtH1), where a single sequence must be elected from SEQ ID Nos: 1-8, 49 and 80-87.

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Group XXVI, claims 43-44, drawn to a screening method to identify a tumour-specific DNA by using DNA from *Haliotis tuberculata* hemocyanin protein 2 (HtH2), where a single sequence must be elected from SEQ ID Nos: 9-15, 50-53 and 88-95.

Group XXVII, claims 43-44, drawn to a screening method to identify a tumour-specific DNA by using DNA from *Megathura crenulata* hemocyanin protein 1 (KLH1), where a single sequence must be elected from SEQ ID Nos: 17-19, 54-56 and 96-101.

Group XXVIII, claims 43-44, drawn to a screening method to identify a tumour-specific DNA by using DNA from *Megathura crenulata* hemocyanin protein 2 (KLH2), where a single sequence must be elected from SEQ ID Nos: 20-24, 57-62 and 102-108.

2. The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Keller et al. disclose on p. 31, figure 4, and p. 32, figure 5, the amino acid sequences of the functional domains f, g, and h from *Haliotis tuberculata* hemocyanin protein 1 (HtH1). Specifically the h domain from Keller et al. is identical to SEQ ID No: 30 of the instant application with the exception of an added aspartate on the C-terminal end. However, since the claim language is open, an extension to the claimed sequence is acceptable. Thus the special technical feature that links all of the claims together is not novel over the prior art and lack of unity of invention is found to be proper.

3. Furthermore, each individual sequence represented by a SEQ ID No: is patently distinct from one another because each individual sequence has its own distinct amino acid sequence that is significantly different from all others and thus would require a separate search. Furthermore, as is pointed out on page one of the specification, each domain of hemocyanin, where a domain is represented by an individual SEQ ID No: in the instant application, differs from the others immunologically. Therefore, each SEQ ID

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No: has its own unique immunological function. Applicant is further reminded that this is

**NOT an election of species.**

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached Monday to Friday, 8.30am to 5.00pm.

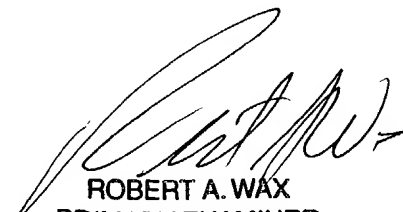
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Smm*

SMM

01 November, 2004

  
ROBERT A. WAX  
PRIMARY EXAMINER  
*AA Unit 1653*